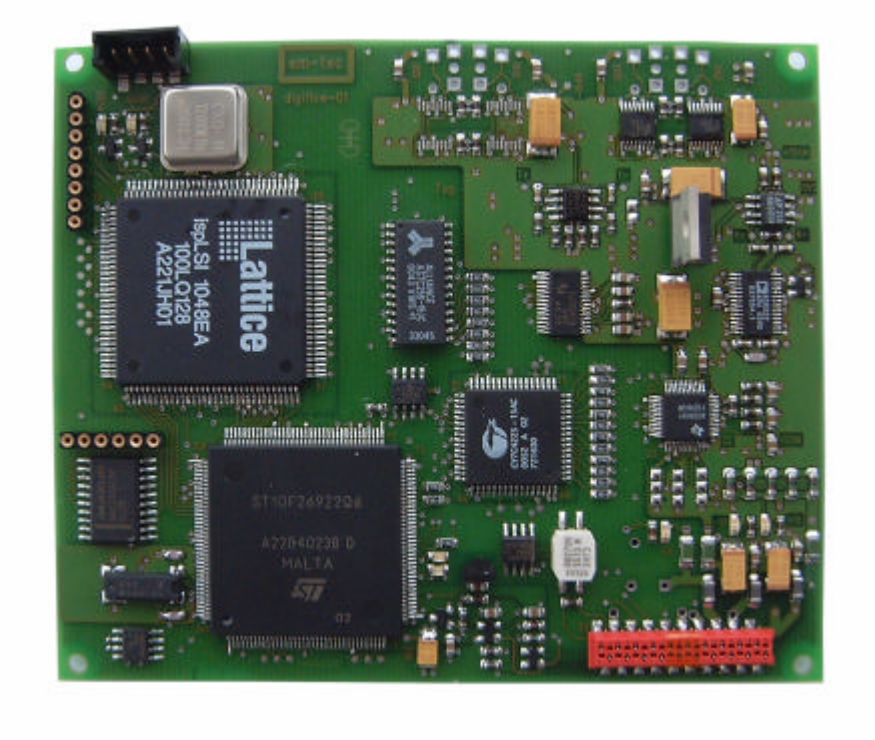
emtec

DIGIFLOW

the

OEM Ultrasonic Flow Measuring Board



- User Manual -

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2. Safety Instructions

Read this User Manual carefully before you start the installation!

Terms and Definitions

DIGIFLOW	OEM ultrasonic transit-time flow measuring board which must be used in combination with a Transducer.
Transducer	Device to transmit and receive ultrasound signals which will be analysed by the DIGIFLOW board.
Main Unit / User System	Host system into which the DIGIFLOW was integrated by the customer.
Customer / User	Person or company who uses the DIGIFLOW as OEM part in combination with their own system.

Indication

The DIGIFLOW is indicated to measure the liquid volume flow in flexible plastic tubes. It was especially designed for the integration into different user systems. For this reason the intended use will be dependent on the user application of the main unit. The environmental parameters and technical specifications, which must be strictly adhered to, are described on following pages.

Contraindication

The DIGIFLOW is only constructed and sold for the above mentioned purposes.

Medical applications:

In case that the DIGIFLOW shall be integrated in a medical system the user has to observe the following instructions.
The DIGIFLOW was designed to monitor the function of the equipment which generate the flow (e. g. oxygenator/pump), but NOT to monitor vital patient parameters like a patient monitor. This unit shall NOT be intended for use as the sole basis for diagnosis without confirmation by another established medical procedure. Should the unit be used to control the liquid volume flow, the user has to analyse the risk of the application and if necessary, do flow board independent actions to minimize this risk.

Liabilities and Responsibilities

The user is responsible to use, check and maintain the DIGIFLOW according to this user manual. Furthermore he is liable and responsible for updating approvals and reviewing the technical file of the main unit in which the DIGIFLOW was included.
em-tec is not liable or responsible for any consequences arising out of use of the DIGIFLOW which is not compare with the instructions or specifications of this manual.

General Safety Instructions

The DGIFLOW was developed and manufactured according to the newest technologies and production procedures (state-of-the-art).
Before installation the user has to read this manual carefully to prevent hazards and injury for the user or damage to the user system in case of improper use.
The service for the DIGIFLOW may be carried out by *em*-tec only. For this reason the malfunctioning systems must be shipped back to *em*-tec.
em-tec recommends that the system should be calibrated every 2 years.

Electrical Safety

The integration of the DIGIFLOW in the customer unit or the combination with other units must be realised according to IEC 60601 and further relevant national standards.

Use of an electrical cauterising knife

If you allow a cauterising knife to touch the measuring system or the extracorporeal tubes the flow display could be inaccurate.

Cleaning and Disinfection

After use of the DIGIFLOW system the Transducer should be cleaned, i.e. open the enclosure, remove the tube and eliminate splattered blood or gel from the housing with a lint-free cloth. Use only agents for cleaning and disinfection which have been tested and approved by your local Health Authority.
Work in a well-ventilated room. Pay attention that no agents ingress into the housing. Do not dip the whole Transducer into fluids!

Solvents

Chemical solvents like alcohol, aether, acetone etc. must not be used in or on any parts of the DIGIFLOW System. Do not spill anaesthetics on the unit or on any accessories. Chemicals like Foran (Isofluoran) could be very damaging for the system.

3. Symbols and Abbreviations

Warning, must be observed strictly

Important instruction

Alternating current (AC)

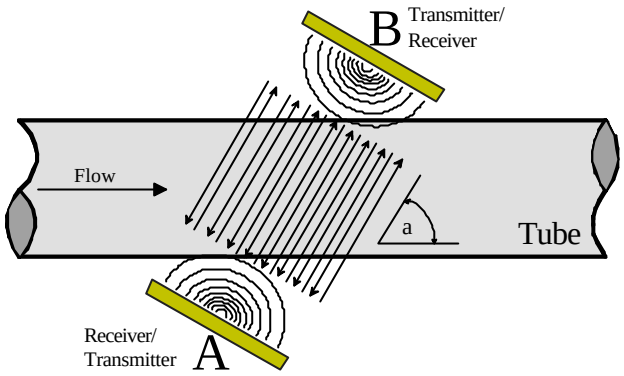
Type BF, Safety class according VDE 0750 Part1

IPX1

IPX1, Protection against or from dripping water

Connection for potential equalisation

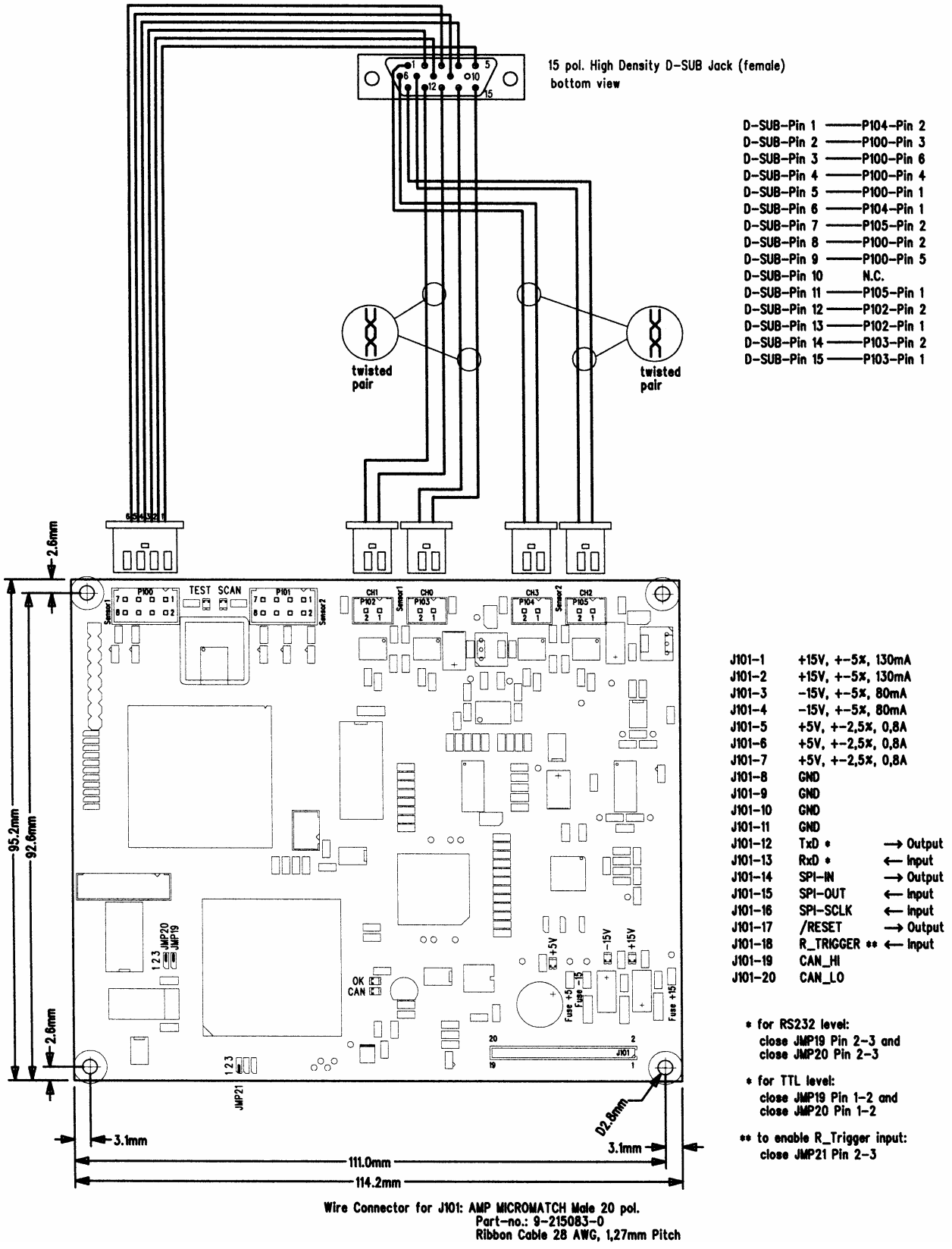
4. Theory of Measurement



The DIGIFLOW uses the ultrasonic transit-time method to measure volumetric flow through the tube. Liquid is flowing through the Transducer and carries with it the sound wave produced by the piezoceramic (A and B). The measurement is made twice; once upstream and once downstream. The transit time is determined in both cases and the difference is proportional to the volumetric flow. Other factors such as used tube size, ultrasonic frequency, fluid type, temperature and transducer characteristics must considered for determination of the actual volumetric flow.

5. Specifications of the DIGIFLOW Board

5.1 Dimensions and Pin Assignments



5.2 Description of the Interfaces

Board	Signal	Description
J101-Pin 1	+ 15V, ± 5%	Operating voltage, supply current of 130 mA is required
J101-Pin 2	+ 15V, ± 5%	
J101-Pin 3	- 15V, ± 5%	Operating voltage, supply current of 80 mA is required
J101-Pin 4	- 15V, ± 5%	
J101-Pin 5	+ 5V, ± 2,5%	Operating voltage, supply current of 800 mA is required
J101-Pin 6	+ 5V, ± 2,5%	
J101-Pin 7	+ 5V, ± 2,5%	
J101-Pin 8	GND	Ground connection
J101-Pin 9	GND	
J101-Pin 10	GND	
J101-Pin 11	GND	
J101-Pin 12	TxD *	Transmitter serial data output from serial port
J101-Pin 13	RxD *	Receiver serial data input
J101-Pin 14	SPI-IN	SPI-interface input
J101-Pin 15	SPI-OUT	SPI-interface output
J101-Pin 16	SPI-SCLK	SPI-interface clock input
J101-Pin 17	/RESET	Input signal to restart the DIGIFLOW board (low active, TTL level)
J101-Pin 18	R_TRIGGER **	Input signal to define the measurement period of the flow measurement (positive edge sensitive)
J101-Pin 19	CAN_HI	CAN 2.0B interface high line
J101-Pin 20	CAN_LO	CAN 2.0B interface low line

Option	Description
*	For switching to the RS232 level close JMP19 Pin 2-3 and JMP20 Pin 2-3
*	For switching to the TTL level close JMP19 Pin 1-2 and JMP20 Pin 1-2
**	To enable the R_TRIGGER input close JMP21 Pin 2-3

Settings of the serial communication port

Baud rate: 38400 Baud
Data bits: 8
Stop bits: 1
Parity: none

5.3 Technical Data of the DIGIFLOW Board

Principle of measurement:	ultrasonic transit-time method
Board size:	114,2 x 95,2mm
Total height:	about 40mm (incl. space bolts and supply cables)
Connection to the Transducer:	enclosed cable set
Connection to the main system:	AMP MICROMATCH Male, 20 pole
Power requirements (DC):	+ 5V, ± 2,5%, 800mA + 15V, ± 5%, 130mA } 6 Watts - 15V, ± 5%, 80mA
Interfaces:	- RS232 (CAN and SPI on request) - R-Trigger (TTL Input)
Max. scan rate:	1000 Hz
ADC sampling rate:	36 MHz
Transmitter frequency range:	15 kHz to 18 MHz, different patterns possible, resolution 8 bit
Zero flow offset adjustment:	yes
Flow range:	0 to 9.99 LPM
Flow resolution:	0.01 LPM
Flow accuracy:	0.0 to 1.0 LPM: ± 0.1 LPM + offset drift 1.1 to 9.99 LPM: ±7 % of actual value + offset drift
Flow offset drift:	max. 0.05 LPM

6. Specifications of the Clamp-on Transducer

6.1 Technical Data and Range of Transducer

Transducer Type	Tube Size	Flow Range	Dimension W x H x D
COT-012-332A	1/2” x 3/32”	20 lpm	60 x 28 x 41
COT-038-332A	3/8” x 3/32”	15 lpm	54 x 25 x 38
COT-014-116A	1/4” x 1/16”	8 lpm	52 x 20 x 35

Protection class (IP code):	IPX1 - protected against dripping water
Material of the housing:	aluminium
Type of probes:	Z-Type (X-Type on request)
Cable:	5 x 2 wires, 0,05mm², shielded twisted pair, 2 m
Connector:	15 pole High Density D-SUB
Tube material:	PVC, silicon (other materials on request)
Medium inside the tube:	water, blood (other mediums on request)

7. Installation of the DIGIFLOW Board and Transducer

The DIGIFLOW system consists of electrostatic sensitive devices. Handle only at static safe work stations according to IEC 61340-5-2!

7.1 Environmental Requirements

Temperature limits:

Operating:	17°C to 45°C
Transportation:	–18°C to 55°C
Storage:	–18°C to 45°C

Relative humidity:

Operating:	30 % to 75 % non-condensing
Transportation:	10 % to 96 % non-condensing
Storage:	10 % to 96 % non-condensing

Atmospheric pressure:

Operating:	87 to 106 kPa
Transportation:	70 to 106 kPa
Storage:	70 to 106 kPa

7.2 Installation of the DIGIFLOW Board

Install the DIGIFLOW board according to IEC 60601 and further relevant national standards!

The board must be fixed inside the main unit by 4 screws (recommended 2,5 mm in diameter) in combination with plastic space bolts (recommended 10 mm).

Ensure that the board is fitted without any tension.
All environmental conditions must meet the prescribed specifications (see chapter 7.1).

The connection between the DIGIFLOW board and the Transducer was realised by a cable set which was enclosed the shipment. The included HD SUB-D jack should be mounted on the housing of the main unit (use the enclosed screws). Should it be necessary to shorten the cable use the pin assignment which was listed on page 7.

After the mechanical installation connect the prescribed supply voltages and signals to the J101 on board AMP MICROMATCH male.

Attention! A short circuit resulting from an incorrect assignment of the wires will damage the DIGIFLOW system.

If the DIGIFLOW board was successful installed a start up message will be transmitted via the serial data communication port to the main unit. Status information such as the following will be edited by using a TVI925 terminal emulation.

```
             DIGIFlow FlowMeter
            --------------------
Software Revision: V1.00  Build from: Sep 22 2003  13:51:31
Serial No: DigiFlow 01

SELFTEST

IRAM internal check:     PASSED
External WDT check:       PASSED
Flash ROM on chip check: PASSED        XPER/XRAM on chip check: PASSED
CAN1_RAM on chip check:  PASSED        CAN2_RAM on chip check:  PASSED
EEPROM check:            PASSED

Offset Check[mV]: 0   (0 mV)        +5V Check[mV]: 596   (4768 mV)
+-15V Check[mV]: 1023   (4092 mV)
Temperature check:       426 PASSED

Self-Test  PASSED

Press 'esc'-Key for Service Menue!
```

After showing the results of the initial self test the DIGIFLOW board transmits a data string such as the following via the serial communication port to the main unit:

Parameter	1	2	3	4	5	6	7	8	9
String	00	08	+1592	+1590	+113	+0	+1254	+1590	+454

The data string consists of the following parameters separated by blanks:

Parameter 1: error byte (hex) of the DIGIFLOW board (see troubleshooting, too)
Parameter 2: status information (hex) of the flow measurement board DIGIFLOW
- Bit 7: Sensor 1 connected
- Bit 6: currently unused
- Bit 5: Signal amplitude below 39%
- Bit 4: currently unused
- Bit 3: PVC tube detected
- Bit 2: Silicone tube detected
- Bit 1: flow values not ok or amplitude below 49%
- Bit 0: temperature of flow board to high (> 65 °C)

Parameter 3: mean flow value integrated over 1 second in ml/min
Parameter 4: actual flow value in ml/min
Parameter 5: signal amplitude of the acoustic receiving signal in %
(100% is set to signal amplitude of 2.66 V)
Parameter 6: additional information for calibration purposes (only for service)
Parameter 7: measured transition time in picoseconds
Parameter 8: integrated flow value from R-Trigger to R-Trigger signal (if enabled by jumper setting) or integrated flow value over 10 seconds
Parameter 9: board temperature in 0.1 °C

The data string will be finished by a carriage return (0x0d) and a line feed (0x0a) character.

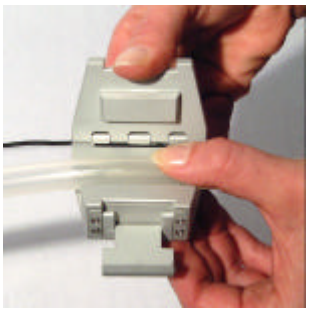
Temperature Control Function

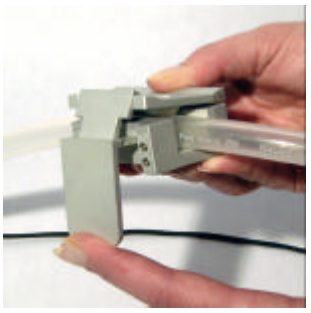
The board temperature will be checked by the µController continuously (parameter 9 of data string). A temperature above 65°C will be set in the status byte. The temperature alarm flag in the status byte will be cleared if the board temperature decreases below 60°C. Should the board temperature further increase above 75°C a temperature error will be set in the error byte (see chapter “Troubleshooting”).

The temperature control function should be implemented for control purpose only. Independent thereof has to be enough cooling inside the housing in which the DIGIFLOW will be built in (< 45°C).

7.3 Mounting of the Transducer

Select the Transducer according to the used tube size and connect it to the installed DIGIFLOW board via the 15 pin High Density D-SUB jack. If the unit is running properly the included EEPROM will be readable and the DIGIFLOW board will receive the stored Transducer data automatically. If you should have problems, please see also the chapter „Troubleshooting“.
Before you start the measuring, you have to clamp-on the Transducer to the tube according to the following instructions.





Press the tube in the housing and close the Transducer.

The arrow which you can see on the enclosure should be in flow direction, so you will get positive flow values.

Pay attention that the tube is not damaged or deformed on the position where you want to clamp on the Transducer. The tube should also be straight (unbent) for reaching laminar flows and exact measuring values.

In case that you do not attain enough ultrasound coupling the tube must be greased by coupling gel before you clamp-on the transducer.

Use the original coupling gel (Order No: 10385) only! We do not guarantee sufficient ultrasound coupling for a longer measurement time if you should use other gels.

7.4 Troubleshooting

During the start up and normal operation of the DIGIFLOW several self tests are running. The result of these tests will be transmitted via the serial communication port to the main unit. In case that a test fails an error code will be stored in the transmitted error byte. Additionally, an error indication will be displayed by the OK-LED which is located on the top side of the board (see page 7). If the unit is running properly the LED is on. In case of error detection the LED will be switched off.

Example of a failed self test:

```
             DIGIFlow FlowMeter
            --------------------
Software Revision: V1.00  Build from: Sep 22 2003  13:51:31
Serial No: DigiFlow 01

SELFTEST

IRAM internal check:     PASSED
External WDT check: PASSED
Flash ROM on chip check: PASSED        XPER/XRAM on chip check: PASSED
CAN1_RAM on chip check:  PASSED        CAN2_RAM on chip check:  PASSED
EEPROM check:            FAILED

Offset Check[mV]: 0   (0 mV)        +5V Check[mV]: 596   (4768 mV)
+-15V Check[mV]: 1023   (4092 mV)
Temperature check:       426 PASSED

Self-Test  FAILED
```

A data string with error indication is following:

```
19  2A   +1087  +1090  +113     +0  +1089     +0     +0
```

Parameter1 (error byte) = 0x19 → EEPROM test error

Further error indications are described on the following page.

Description of the Error Byte:

0x00	no error
0x01	FLASH error at test STP0
0x02	FLASH error at test STP1
0x03	FLASH error at test STP2
0x04	FLASH error at test STP3
0x05	FLASH error at test STP4
0x06	FLASH error at test STP5
0x07	RAM error at test STP0
0x08	RAM error at test STP1
0x0A	RAM error at test STP2
0x0B	RAM error at test STP3
0x0C	RAM error at test STP4
0x0D	RAM error at test STP5
0x0E	Watch Dog Timer defect
0x0F	error in task handling
0x10	error during JMP-Check
0x11	internal ADC error (status STP0)
0x12	internal ADC error (status STP1)
0x13	internal ADC error (status STP2)
0x14	internal ADC error (status STP3)
0x15	internal ADC error (status STP4)
0x16	internal ADC error (status STP5)
0x17	internal ADC offset error
0x18	+5V test error
0x19	EEPROM test error
0x1A	Board temperature error (> 75°C)
0x1B	+15V check error
0x1C	-15V test error
0x21	EEPROM CRC error
0x22	Calibration factor inconsistent

8. Order and Service Procedures

DIGIFLOW

DIGIFLOW Board including Cable Set and User Manual	Order No: 11088

Accessories

Transducer (COT-012-332A), tube size:1/2" x 3/32"	Order No: 11056
Transducer (COT-038-332A), tube size:3/8" x 3/32"	Order No: 11048
Transducer (COT-014-116A), tube size:1/4" x 1/16"	Order No: 11032
Ultrasound Coupling Gel	Order No: 10385

Please contact our sales department if you want order the DIGIFLOW system or accessories. Do not hesitate to get in touch with our salesmen if you should have any questions.

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In case that a unit seems to be malfunctioning, please inform our service department before you send it to *em*-tec. Our support engineers will help you solve the problem. Please use the original package if you send back the malfunctioning system to em-tec. Enclose the shipment a detailed description of the failure. Name and phone number or e-mail address of the person who is able to give further information would be helpful.

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